

United States Senate

WASHINGTON, DC 20510

February 9, 2005

Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

Congratulations on your appointment and confirmation as Secretary of Health and Human Services.

Cervical cancer is a largely preventable disease. Yet according to the American Cancer Society, an estimated 13,000 new cases of invasive cervical cancer are diagnosed annually and over 4,000 women die of the disease every year. Tens of thousands of others will be treated for related pre-cancerous conditions.

Nearly all cases of cervical cancer are directly associated with human papillomavirus (HPV). The Centers for Disease Control and Prevention (CDC) estimates 20 million Americans are currently infected with HPV and 5.5 million Americans become infected with HPV every year. HPV infection is also associated with other cancers and more than one million pre-cancerous lesions that impact both women and men.

Studies have repeatedly demonstrated over the past decade that condoms do not provide effective protection against HPV infection and the risk of pervasive HPV infection and cancer increase with the number of sexual partners and the younger the age of initiation of sexual activity.

Public Law 106-554, signed by President Clinton more than four years ago, directs the Food and Drug Administration (FDA) to reexamine condom labeling to ensure that such labels are medically accurate regarding the lack of effectiveness of condoms in preventing HPV infection. This law also requires the CDC to educate the public and health care providers about HPV infection and how HPV can be prevented. This law became necessary because FDA and CDC had failed to educate the public about HPV.

Over the four years since this law was signed, both agencies have continued to abdicate their responsibilities to protect the public from HPV by repeatedly delaying and avoiding compliance with the law. This continued delay undermines the scientific integrity of both agencies and further jeopardizes the confidence of the public and Congress in the agencies' ability to fulfill their mission.

We are also concerned about a \$10 million study financed by the National Institutes of Health and conducted by the H. Lee Moffitt Cancer Center & Research Institute. This study will test minority men for HPV, but will not disclose test results to those who are infected. Withholding this information will deny study participants the ability to protect current or future partners from HPV infection. The study abstract also states, "we hypothesize that current condom use and circumcision confers reduced risk of incident HPV infection." The truth is studies-- including NIH studies-- have concluded that condoms do not provide effective protection against HPV infection. This study, therefore, is based upon an unscientifically sound premise and raises serious ethical questions.

We urge you to immediately direct:

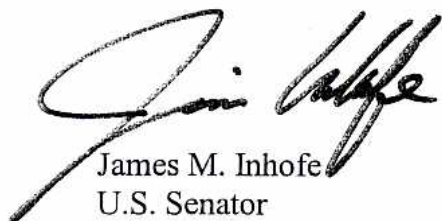
- (1) The FDA to immediately comply with the law by requiring condom labels to be medically accurate regarding the lack of protection against HPV infection;
- (2) The CDC to comply with the law by launching a large scale effort to educate the public that only abstinence and mutual faithfulness can prevent HPV infection and condoms do not provide effective protection against HPV; and
- (3) The NIH to disclose to those test subjects diagnosed with HPV that they are infected with HPV and counseling on how to protect their own health and protect current or future partners from HPV infection.

We would also request:

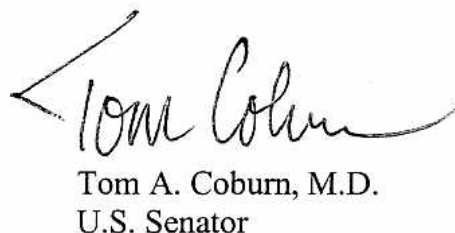
- (1) An explanation for the continued delay by the FDA in complying with this four year old law;
- (2) A complete listing of all participants in all the CDC consultation meetings related to Public Law 106-554 including dates and locations of these meetings;
- (3) Copies of all hand outs, documents and papers reviewed in the CDC consultation meetings; and
- (4) An explanation from NIH on the ethics of withholding diagnosis from infected test subjects, including any ethical reviews that were conducted.

Thank you for your attention to this matter. We look forward to working with you in protecting the health of all Americans.

Sincerely,



James M. Inhofe
U.S. Senator



Tom A. Coburn, M.D.
U.S. Senator